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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 658,835	09 08 2000	Jonathan P. Duvick	1134R	2865

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1658

DATE MAILED: 10 02 2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/658,835

Applicant(s)

DUVICK ET AL.

Examiner

Medina Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 10, 13-32 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-19 and 33-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Receipt is acknowledged of Applicant's response to the requirement for restriction filed 06/18/02. Applicant elected Group I, with traverse, corresponding to claims 1-9, 11-12 and 33-38. Applicants further elected the inventions L and N, corresponding to SEQ ID NO:50 encoding SEQ ID NO:51 and SEQ ID NO:24. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, the restriction requirement is made FINAL.

Claims 1-9, 11-12, 33-38 and SEQ ID NO:50-51 and 24 are under examination.

Claims 10, 13-32 and 39-41, and SEQ ID NO:5-6, 10-11, 22-23, 26 32-33, 35-46, 48-49, and 52 are withdrawn as being directed to non-elected inventions.

Objections

The specification is objected to because of the following informalities: for example, page 64, line 12, recites sequence without a sequence identifier. Applicant must submit a new CRF and paper copy of the Sequence Listing, including the sequence on page 64. Applicant must also amend the specification to include the SEQ ID NO for the sequence.

The claims are objected to for the following informalities: claims that recite non-elected inventions should be amended accordingly.

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Sequence Listing

2. Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

3. Initialed and dated copy of Applicant's IDS form 1449, Paper No. 6 is attached to the instant Office action.

Drawings

4. The drawings filed in the instant application are approved.

Priority

The status of nonprovisional parent applications, listed in page 1 of the specification, should be updated.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim Rejections - 35 USC § 112

6. Claims 1-9, 11-12, and 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 1, SEQ ID NO:33 is listed as a polypeptide in part (a) and as a polynucleotide in part (b). Correction is required. Dependent claims 2-9 and 11-12 are included in the rejection.

In claim 8, "a" should be changed to ---the- isolated--, for proper dependency.

Claim 9 is indefinite because "plant of claim 7" lacks antecedent basis. It is suggested that "claim 7" be replaced with ---claim 8---; and "a" should be changed to --the---. Also, the claim does not recite --- transformed seed--- and it is unclear if the seed also contains the transgene. Applicants should note that due to chimerism, not all of the cells from a transgenic plant will comprise in their genome the transgene construct. In order for the claims not to read the product of nature, it is suggested that the claims be amended to recite ---, wherein the seed comprises the isolated polynucleotide---.

In claim 33, ---isolated---, should be inserted before "APAO", for clarification. Dependent claims 34-38 are included in the rejection.

In claim 34, ---sequence" should be inserted before "identity", for clarification.

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In claims 11 and 35, "ESP1" is not defined in the specification and it is unclear what the abbreviation stands for.

Claim Rejections - 35 USC § 112

7. Claims 1-9, 11-12 and 33-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated APAO encoding polynucleotide linked to an esterase encoding polynucleotide from *Exophiala spinifera* and *Rhinocladiella atrovirens* or the bacteria of ATCC 55552 isolates from maize seed, and plant cell and plants comprising said polynucleotides, does not reasonably provide enablement for any and all APAO and fumonisin esterase encoding polynucleotides from any source or polynucleotide sequences having at least 70% identity to SEQ ID NO:50, or host cells comprising them. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims drawn to any and all isolated APAO or fumonisin esterase encoding polynucleotides or polynucleotides having at least 70% sequence identity to the disclosed sequences are not

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supported by an enabling disclosure, taking into account the the *In re Wands* factors. *In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

In the specification, Applicants provided guidance only for the polynucleotides of *Exophiala spinifera* (ATCC Accession No. 74269), *Rhinocladiella atrovirens* (ATCC Accession No. 74270) and the bacteria of ATCC Accession No. 55552 isolates from maize seed encoding fumonisin esterases of ESP1 and fumonisin APAO to reduce pathogenicity of a fungus producing fumonisin in fusarium sensitive crop plant/plant cells. Applicant has not provided guidance for the obtention of other fumonisin esterase or APAO encoding polynucleotides. While fumonisin degrading enzymes can be obtained from a variety of sources, not all isolates

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are able to degrade fumonisin. For example, US PAT. 6, 025, 188, teaches that several other *Exophiala* species (other than *E. Exophiala*) and non-maize *Rhinocladiella* isolates didn't degrade fumonisin or fumonisin related compounds (column 7, lines 4-9). Applicant has provided no guidance regarding the working conditions necessary to obtain polynucleotides from non-maize *Rhinocladiella* and non- *E. Exophiala* sources capable of encoding a polypeptide having fumonisin degrading activity.

Applicant has not provided guidance for any modifications to SEQ ID NO: 50 which resulted a polynucleotide having at least 70% sequence identity thereto and still encoding a polypeptide having APAO activity. The state of the prior art teaches that sequence identity does not necessarily mean similar function. For example, Lazar et al. (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1252 (U))), teach a mutation of aspartic acid 47 and leucine 48 of a transforming growth factor alpha results in different biological activities (Title). Broun et al (Science, 13 November 1998, Vol. 282, pp. 131-133 (V) teaches as few as four amino acid substitutions can change an oleate 12-desaturase activity to a hydroxylase (Abstract). Applicants should note that the

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nucleic acids encoding Lazar's and Broun's proteins (mutated and original) would have more than 70% sequence identity. Therefore, it is unpredictable whether any and all polynucleotides that share 70% sequence identity to the disclosed sequence would encode a polypeptide having APAO activity, especially when coexpressed with other enzymes.

Therefore, given the breadth of the claims; lack of guidance; unpredictability; the state of the art as discussed above; and lack of working examples, undue trial and error experimentations would have been required by one skilled in the art to practice the invention as broadly claimed.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

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Claims 1-9, 11-12 and 33-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to a multitude of APAO and fumonisin esterase encoding polynucleotides as well as any and all polynucleotides having at least 70% sequence identity to SEQ ID NO:50 and encoding a polypeptide having APAO activity. These are genus claims. Applicant described the polynucleotide sequences from *Exophiala spinifera* (ATCC Accession No. 74269) and *Rhinocladiella atrovirens* (ATCC Accession No. 74270) or the bacteria of ATCC Accession No. 55552 isolates from maize seed encoding a polypeptide having fumonisin esterase or APAO activity. Applicant has not described specific structural, physical and/or chemical properties common for all fumonisin esterase or APAO encoding sequences. A review of literature does not indicate that such characteristics would be well known by a skilled artisan. Therefore, the disclosure of a single or few species within the

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genus would not provide adequate written description for all the species within the species, absent more. This is exactly the situation in *Eli Lilly* case where the court has determined that the description of a genus may be achieved by disclosing a representative sample of species falling within the scope of the genus or structural features common to members of the genus, which features constitute a substantial portion of the genus. In this Application, Applicant has neither disclosed a representative sample of species nor provided a structural feature common to all members of the genus. Therefore, the written description requirement is not satisfied. Therefore, the disclosure of polynucleotides from *Exophiala spinifera* (ATCC Accession No. 74269) and *Rhinocycladiella atrovirens* (ATCC Accession No. 74270) or the bacteria of ATCC Accession No. 55552 isolates from maize seed encoding a polypeptide having fumonisin esterase or APAO activity would not provide adequate written description for all APAO and esterase fumonisin encoding polynucleotides as well as all polynucleotides having 70% sequence identity to SEQ ID NO:50 and still encoding an APAO polypeptide. Because Applicant has

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not described the polynucleotides as broadly claimed, plants and plant cells comprising them are not similarly described.

Therefore, weighing all factors above, a person skilled in the art would not recognize from the disclosure that Applicant was in possession of the invention. See, Written Description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices). See, also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Remarks

Claims 1-9, 11-12 and 33-38 are free of the prior art of record.

No claim is allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to

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receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina a. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00AM to 4:00PM and Wednesday-Thursday from 9:00AM to 3:00 PM .

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

September 23, 2002

mai

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